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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
SOUTH WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,669	BRINGE ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-11, drawn to a method of preparing a foodstuff, comprising the steps of a) obtaining a selected foodstuff, and b) adding isolated oil body associated protein to the foodstuff.

Group 2, claim(s) 14, drawn to a composition for treating or preventing hypercholesterolemia comprising glycinin or fragment thereof, and purified oil body associated protein.

Group 3, claim(s) 15, drawn to a composition for treating or preventing hypercholesterolemia comprising β-conglycinin, or fragments thereof and purified oil body associated protein.

Group 4, claim(s) 31, drawn to a composition for treating or preventing hypercholesterolemia comprising basic subunit of glycinin.

Group 5, claim(s) 32, drawn to a composition for treating or preventing hypercholesterolemia comprising B-1b subunit of glycinin.

Group 5, claim(s) 33, drawn to drawn to a composition for treating or preventing hypercholesterolemia comprising α' subunit or a fragment thereof β-conglycinin.

Group 6, claim(s) 34, drawn to a composition for treating or preventing hypercholesterolemia comprising more than 40% β-conglycinin or a fragment thereof.

Group 7, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:1.

Group 8, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:2.

Group 9, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:3.

Group 10, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:4.

Group 11, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:5.

Group 12, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:6.

Group 13, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:7.

Group 14, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:8.

Group 15, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:9.

Group 16, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:10.

Group 17, claim(s) 35, drawn to a composition for treating or preventing hypercholesterolemia consisting of SEQ ID NO:11.

Group 18, claim(s) 45, drawn to a method for the treatment or prevention of hypercholesterolemia comprising isolated soy polypeptide β-conglycinin or a fragment thereof.

Group 19, claim(s) 46, drawn to a method for the treatment or prevention of hypercholesterolemia comprising isolated soy polypeptide glycinin or a fragment thereof.

Group 20, claim(s) 55, drawn to a method for treating or prevention of hypercholesterolemia comprising SEQ ID NO:1 or having an amino acid sequence having at least 95% sequence homology.

Linking Claim

2. Claims 12-13 and 16-30 link(s) inventions 2 through 17. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 12-13 and 16-30. Claims 36-44 and 47-54 link(s) inventions 18 through 20. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 36-44 and 47-54. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups 1 through 20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the

same or corresponding special technical features for the following reasons: The special technical feature of the instant invention is a method of preparing a foodstuff, comprising the steps of obtaining a selected foodstuff and adding isolated oil body associated protein to the foodstuff. Ono T (Japanese patent Publication NO.: Tokkai 2002-101820, published on April 9, 2002) teaches this special technical feature. Ono patent teaches the oil body-like nanocapsule fraction or its dried material containing oil seeds with oleosin protein, preferably the soybean-derived, and these nanocapsules are for coating hydrophobic substance(s) (see Means of solution). The reference teaches a process to preparing oil body-like nanocapsule fraction characterized using oil seeds containing oleosin protein as the starting material (see claim 9) these in the food source, for coating more than one lipid selected from rapeseed oil, fat-soluble vitamins and fish oil (see Means of solution). Therefore, the unity of the invention is broken.

Election

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different additional components: saponin, phytoestrogen, phospholipids, or carbohydrate;

Different soy-based foodstuff: soy flour, soy grit, soy meal, soy flakes, soy milk powder, soy protein concentrate, soy protein isolate, or isolated soy polypeptide,

Different isoflavone: genistein, diadzein, equol, biochanin A, formononetin, naturally occurring glucosides or glucose conjugates,

Carbohydrate: high amylase starch, oligofructose, or soy cotyledon fiber,

Different phospholipids: lecithin, lyso-lecithin, or lecithin with a modified fatty acid composition,

Different saponin: soy saponin A, saponin B, saponin E, sapogenol A, sapogenol B, or sapogenol E,

Different lipoprotein: mammalian lipoprotein, egg yolk lipoprotein, or fat globule membrane protein,

Different 40% of β-conglycinin or a fragment thereof.

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

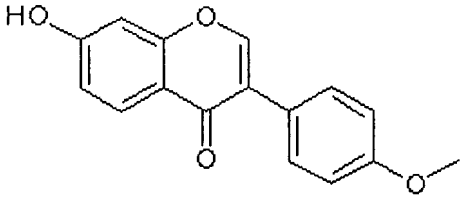
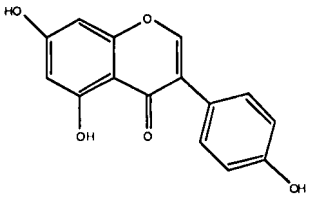
6. For any Group elected, the Applicant is required to elect a single disclosed species of lipoprotein, foodstuff, saponin or phytoestrogen or phospholipids or carbohydrate. Please note, if an election is made only of a compound, for example glycinin without an election of additional additives, such as saponin (sapogenol E), it would be treated as an election of glycinin only and examined only for a composition comprising glycinin.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-2, 8, 10-55.

The following claim(s) are generic: None.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different additional components such as saponin, phospholipids are structurally distinct, thus patentably independent and distinct. For example, saponin is a glycoside while phospholipids are lipids having a phosphate group. Further, search for one would not necessarily lead to the other. Different soy-based foodstuffs are patentably independent and distinct because of the amino acid content, leading to distinct structures. Further, search for one would not necessarily lead to the other. Different isoflavones are patentably independent and distinct because of different structures. For example, formononetin has the structure  while genistein has the structure  . Further, search for one would not necessarily lead to the other. Different carbohydrates are patentably independent and distinct because of the different structures. Further search for one would not necessarily lead to the other. Different phosphoproteins and lipoproteins are patentably independent and distinct because of their distinct structures. For example, lyso-lecithin is a lecithin with strong hemolytic properties, and is metabolized from lecithin by removal of its terminal fatty acid radical. Thus lecithin and lyso-lecithins have different structures. Further, search for one would not necessarily lead to the other. Different lipoprotein: mammalian lipoprotein, egg yolk lipoprotein, or fat globule membrane proteins are patentably independent and distinct because of the source and the structures are distinct. Further search for one would not necessarily lead to the other. Different 40% of β-conglycinin or a fragment thereof are patentably independent and distinct because the amino acid content would be different. β-conglycinin from chain C (GenBank Accession # 1IPKC) has 416 amino acids. A protein having more than 40% of β-conglycinin means a protein having at least 167 amino acid residues. The difference in structure is vast due to the 40% limitation. Further, search for one would not necessarily lead to the other.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

ANISH GUPTA
PRIMARY EXAMINER